§ 880.5270 Neonatal eye pad.

(a) *Identification.* A neonatal eye pad is an opaque device used to cover and protect the eye of an infant during therapeutic procedures, such as phototherapy.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 880.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180 of this chapter, with respect to general requirements concerning records, and § 820.198 of this chapter, with respect to complaint files.

[45 FR 69682, Oct. 21, 1980, as amended at 65 FR 2318, Jan. 14, 2000]

§ 880.5300 Medical absorbent fiber.

(a) *Identification.* A medical absorbent fiber is a device intended for medical purposes that is made from cotton or synthetic fiber in the shape of a ball or a pad and that is used for applying medication to, or absorbing small amounts of body fluids from, a patient's body surface. Absorbent fibers intended solely for cosmetic purposes are not included in this generic device category.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. If the device is not labeled or otherwise represented as sterile, it is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[45 FR 69682, Oct. 21, 1980, as amended at 66 FR 38804, July 25, 2001]

§ 880.5400 Neonatal incubator.

(a) *Identification.* A neonatal incubator is a device consisting of a rigid boxlike enclosure in which an infant may be kept in a controlled environment for medical care. The device may include an AC-powered heater, a fan to circulate the warmed air, a container for water to add humidity, a control valve through which oxygen may be added, and access ports for nursing care.

(b) *Classification.* Class II (performance standards).

§ 880.5410 Neonatal transport incubator.

(a) *Identification.* A neonatal transport incubator is a device consisting of a portable rigid boxlike enclosure with insulated walls in which an infant may be kept in a controlled environment while being transported for medical care. The device may include straps to secure the infant, a battery-operated heater, an AC-powered battery charger, a fan to circulate the warmed air, a container for water to add humidity, and provision for a portable oxygen bottle.

(b) *Classification.* Class II (performance standards).

§ 880.5420 Pressure infusor for an I.V. bag.

(a) *Identification.* A pressure infusor for an I.V. bag is a device consisting of an inflatable cuff which is placed around an I.V. bag. When the device is inflated, it increases the pressure on the I.V. bag to assist the infusion of the fluid.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 880.9.

[45 FR 69682, Oct. 21, 1980, as amended at 65 FR 2318, Jan. 14, 2000]

§ 880.5430 Nonelectrically powered fluid injector.

(a) *Identification.* A nonelectrically powered fluid injector is a nonelectrically powered device used by a health care provider to give a hypodermic injection by means of a narrow, high velocity jet of fluid which can penetrate the surface of the skin and deliver the fluid to the body. It may be used for mass inoculations.

(b) *Classification.* Class II (performance standards).